HEALTH
AND
WELFARE
IN THE
AGE OF GENETIC INFORMATION

MANAGING THE INDIVIDUAL AND
SOCIAL ISSUES AT STAKE

SUMMARY

OPINION TO THE MINISTRE DE LA SANTÉ ET DES SERVICES SOCIAUX
APRIL 2001

The present Opinion was adopted by the members of the Conseil de la santé et du bien-être at a meeting on the 5th and 6th of April, 2001.

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– Mail : Conseil de la santé
et du bien-être
880, chemin Ste-Foy, RC
Québec (Québec)
G1S 2L2

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The Conseil de la santé et du bien-être was created by law in May 1992. Its mission is to contribute the health and welfare of the population by advising the minister of Health and Social Services, informing the public, encouraging debate and establishing partnerships; its activities focus on these objectives and on the best ways of attaining them.

The Council is composed of 23 members who represent users of health care and social services, community organizations, intervention, research or administration personnel from the health and social sectors, and other sectors whose intervention strategies have an impact on the health and welfare of the population.

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The twenty-first century is likely to be the age of biology, and genetics will assuredly be at the forefront. An unavoidable element in our quest for knowledge, genetics raises social issues and major political questions for which several nations are looking for answers. At the heart of these preoccupations are the redefinition and protection of values and fundamental rights, as well as the "social engineering" ability of the state.

This Opinion does not purport to be an exhaustive examination of these complex questions. Its purpose is to launch and sustain discussion on these topics, and to aid the Ministry of Health and Social Services in defining the role of the state and evaluating the various issues raised as well as the positions and demands of the players in this field, be they individuals, families or populations affected or at risk, clinicians, researchers, public and private investors, insurers, employers or others.

It must be underlined that the development and use of genetics creates interaction among several highly specialized and relatively autonomous sub-systems, including economics, science, technology and health. Over the years, these sub-systems have developed their own rationales, values, demands, goals and work methods and, even taken individually, they often defy understanding and any attempt at outside management[1]. Faced with this complex reality, the state often tends to fall back on self-regulation. But the nature of the stakes raised and the increasing interdependence of these sub-systems call for the exercise of prudence and the application of state responsibility.

To deal with this reality of modern societies, the state needs to rethink its role. In order to understand and manage these sub-systems, it must arrange for the creation of interlinks to learn about these sectors and their various norms. It must also ensure the creation of an "intermediation process" to establish a certain cohesion among these complex, often divergent and conflicting rationales.

It is against this background and from the perspective of the patient, the research subject, the citizen, the worker and the insurance buyer, that the Council, in the first part of this Opinion, studies a certain number of issues engendered by the development and use of human genetics. It is also with these questions in mind that, in the second part of this text, the Council examines the role of the state, enumerates the values that should serve as its guidelines, and formulates recommendations pertaining to the interventions needed.

1. See on this subject Helmut WILLKE, « Trois types de structures juridiques :programmes conditionnels, programmes finalisés et programmes relationnels », dans *L'État propulsif* Contribution à l'étude des instruments d'action de l'État, Charles-Albert Morand, Éditions Publisud, Paris, 1992, 165 pages, p. 65-94.

PART I : THE ISSUES RAISED

Because an exhaustive study of the issues raised by the development and use of human genetics would be impossible, the Council has chosen, in the first part of this opinion, to examine the use of genetic tests in the clinical and research contexts, the use of this type of information for purposes other than medical, particularly for insurance and employment purposes, the needs of research in terms of collection, storage and circulation of genetic material and information, the economic interests involved, and the protection accorded to this material and information[2].

Although there is no standard definition of genetic material and information, we can say that genetic material can be an inexhaustible source of genetic information, and that genetic information is personal information that includes a family and collective dimension. Genetic information reveals information relating to genes but it is important to remember that the gene is not the only determinant of disease (the environment, for instance, is another important determinant). Moreover, genetic information is often predictive and indicative of probability, and is sometimes difficult to interpret. For the purposes of this Opinion, the expression "genetic information" will generally refer to information obtained from genetic analyses and which reveals links between the genes and the disease or a genetic characteristic.

Included in the issues raised are :

The appropriate use of genetic tests

Professionally and socially, the relevance of genetic tests yet to be developed and the conditions for the introduction of these tests into the field of medical services must be examined. Topics of discussion include : the quality and precision of genetic tests; the limits of diagnoses based on them (ex. : in the case of multifactorial diseases, the presence of a specific gene mutation does not necessarily mean that the person will have the disease; on the other hand, the absence of this mutation is not a guarantee that the disease will never manifest itself); the appropriate age to offer certain tests or reveal certain diagnoses; the possible consequences of a diagnosis on the lives of individuals (ex. : late-onset diseases); the nature and effectiveness of curative and

2. See on the subject of the definition of genetic information : Trudo LEMMENS, et Lisa AUSTIN, *Volume, détail et rapidité : Les défis du renseignement génétique*, février 2001, Document préparé pour le Comité consultatif canadien de la biotechnologie, site internet http://www.cbac.gc.ca/francais/; Loïc CADIET « La notion d'information génétique en droit français », dans *La génétique humaine : de l'information à l'informatisation*, Bartha Maria KNOPPERS, Loïc CADIET, Claude LABERGE (sous la direction de), Édition Litec, Paris, 1992, 387 pages, p. 41-75; Sonia LEBRIS, « Vie privée et information génétique – les termes du débat », dans *One World, One Privacy*, Actes de la 22e Conférence Internationale sur la vie privée et la protection des données, Venise, septembre 2000.

preventive treatments available; the sufficiency of consultation services offered; the conditions necessary for genetic screening that will foster the change from an individual approach to a collective one (ex. : screening for heterozygote carriers)[3].

Management of the family aspects of genetic information

Managing the family aspects of genetic information raises the question of disclosure to family members and brings into conflict several principles, values and fundamental rights such as the protection of privacy, the respect of doctor-patient privilege and confidentiality, beneficence, nonmaleficence, autonomy, the right to know and the right of family members not to know.

Since studies have revealed that some genetic tests, including those designed to identify heterozygote carriers of certain diseases or to find a mutation for late-onset diseases, are not frequently requested even by people who know they exist, and considering the state of current knowledge, it is plausible that a large number of family members may prefer not to be made aware of certain genetic information concerning themselves. What must also be taken into account are the possible negative effects psychologically, socially and financially (because of the possibility of discrimination in insurance and employment) of disclosing unsought genetic information, the negative effects of a breach of confidentiality on the doctor-patient relationship, on the demand for genetic services and on the participation of individuals in research in this field.

On the other hand, family members might seek access to the genetic material or information of a member of their family in order to gain information on their own state of health. If the latter refuses to grant access, given the right to confidentiality, the right to autonomy and the principles of beneficence and nonmaleficence, what is to be done?

To resolve these dilemmas, some are of the opinion that confidentiality in the field of genetics must be viewed in terms of the family. The argument is that, if we are interested in genetics from a clinical point of view, it is because we wish to go beyond the immediate diagnosis and see if pertinent information can be gleaned from the family. However a new notion of confidentiality which reflects this reality would imply the redefinition of a value and of a fundamental right, and requires serious reflection before any change in practice is promoted.

3. The heterozygote carrier of a recessive gene is generally not sick himself but he is likely to pass the gene on to his offspring

Dispositions already state that, following the death of individuals and subject to specific conditions, confidentiality can be breached for the benefit of the biological family. Exceptions to the doctor-patient privilege have also been provided for by medical deontology. Before going further, however, and in order to facilitate the interpretation of these dispositions, this reflection is vital.

Management of the indefinite nature of genetic information and of its varying significance over time

These characteristics of genetic information raise the question of long term follow-up of individuals. What should be done with information obtained fortuitously in the course of a prenatal diagnosis? Should it be kept in anticipation of its disclosure because it could eventually become significant for the child (ex. : heterozygote carriers)? What is to be done when genetic information sought for the purpose of prevention indicates at the same time a possible late-onset disease for which there is no prevention (ex. : Alzheimer's disease)?

The use of genetic tests in the context of prenatal diagnosis and the limits to be observed for diseases subject to diagnosis

What is the appropriate reaction to the demand for or offer of genetic tests designed to investigate, at this stage, predispositions to diseases such as cancer, diabetes, Alzheimer's, schizophrenia and manic-depressive illness? The need for serious reflection is obvious.

Establishing the links between genetics and public health

From a scientific standpoint, can genetic screening be an effective public health tool, one that would contribute to improving the population's state of health? If this is the case, is it an ethically acceptable tool? Should we try to eradicate certain hereditary diseases through genetic screening programs? This is the crux of a necessary debate over the existing or potential link between genetics and public health[4].

The conception and planning of genetic services pertaining to the field of public health constitutes for the Council one of the major challenges to be tackled by the authorities responsible for the normative framing of developments in genetics. The subordination of procreative choices to a populational approach to birth-planning policy and prevention of the transmission of genetic abnormalities presents an objective

4. ASSOCIATION POUR LA SANTÉ PUBLIQUE DU QUÉBEC (ASPQ), *Les enjeux éthiques en santé publique*, Acte du colloque tenu les 20 et 21 mai 1999, à Montréal, 187 pages, à la p. 166.

risk of slipping towards discriminatory practices which are objectionable both ethically and legally. This does not mean questioning all diagnostic and genetic screening programs since some allow for the attainment of well defined goals. This is the case, for example, of current neo-natal screening programs and of some sequential screening for heterozygote carriers. There is, however, a considerable amount of reflection and research yet to be done before any new program is approved. What is meant by the term "prevention" used in reference to the transmission of genetic abnormalities? In what respect do people suffering from, or carrying, genetic abnormalities constitute a public health problem? Accordingly, would it be justified to suspend certain fundamental rights, as is done to prevent the spread of infectious diseases?

Genetic discrimination in the insurance and employment sectors, the risk of social exclusion and insurers and employers' position of power

The foreseeable use of genetic information for purposes other than medical poses the risk of the emergence of a new form of discrimination and social exclusion. This risk, examined here in the contexts of insurance and employment, might also be encountered in the public sector which could be inclined to use this type of information for exclusionary purposes, particularly in the social services and immigration sectors.

As a rule, the use of genetic information in the field of insurance should be allowed only if certain minimal conditions are met, that is the existence of reliable actuarial data allowing for an accurate classification of genetic risks, and the use of tests whose reliability, predictive value and sensitivity are acceptable. That being said, given the current state of knowledge, except in the case of monogenic diseases, these conditions cannot be met.

The affordability of insurance, especially life insurance, is in the interest not only of individuals but also of society as a whole because, for many, life insurance allows for the protection of dependents and gives access to certain economic activities. In this same perspective, the fate of people who could be totally deprived of insurance is also a cause for concern.

In the context of employment, allowing the use of genetic information and tests in the evaluation and selection process provides the employer with a host of information whose relevance must be questioned. As was stated by the Human Rights Tribunal : "If the employer has the right to select employees, exercising this right must occur within the parameters set by society[5]".

5. *C.D.P.Q. (Gaumond) c. S.T.C.U.M., supra* note 35, on p. 2080 (our translation).

The place of genetic information in the employment sector must be determined in light of the fact that, if genetic diagnosis and genetic surveillance can be valuable tools in preventing work-related illnesses and accidents, they can also lead to the systematic exclusion of individuals for their own good and be used as an option to improving the work place.

We must take into account that, if the dispositions designed to counter discrimination and protect privacy play an important role in protecting individuals against discrimination in the contexts of insurance and employment, the position of power of the insurer or the employer over the buyer of insurance, the employee or the job applicant calls for caution. In this perspective and given the lack of reliable data on the sensitivity of genetic tests, the Council deems it appropriate to follow the international trend and to limit as much as possible the use of genetic information in the insurance and employment sectors.

The importance given to research in genetics, the economic interests involved, its rapid development and its needs in terms of collecting, storing and circulation of genetic material and information

One of the purposes of fundamental research in the field of human genetics is to decode and understand all the genetic information contained in the human organism. Thus, genetic material and information represent the raw material in this field of research which is raising great enthusiasm and considerable economic stakes nationally and internationally. The Human Genome Project, its scope and its recent developments, the creation of Genome Canada and Genome Québec, the existence of other infrastructures of research in this field in the province of Québec, as well as considerable investments from the biotechnological and pharmaceutical industries are all factors that make research in genetics a fast-evolving and ever-expanding field of activities. There is talk of a “genetic revolution” and it is in this context that the collecting, storing and circulation of genetic material and information needed for this type of research take place.

The fact that the province of Québec, given the profile of its population, is an interesting territory for genetic research, the fact that it possesses a favorable research infrastructure (ex.: Genome Québec, FRSQ, RMGA, IREP, etc.) and the fact that development in this sector is linked to economic growth are sure signs of the importance research in this field and the collecting of genetic material and information will acquire in years to come.

In this context and given the repercussions that genetic information can have, it is clearly important to involve the public in decisions related to the creation of a

population-wide database of genetic material and information. Would Québec society be in favor, for instance, of the creation of data and tissue banks such as those in Great Britain and Iceland?[6] It is also clearly important to assure the protection of privacy and the effectiveness of norms governing the collection, conservation, use and circulation of this material and information.

Furthermore, even though ethics is an integral part of the structures of research, the promoters of research and the developers in this sector cannot be its sole regulators. The emergence of a critical mass concerned with ethics must be favored to avoid the development of a monopoly, of a one-vision system. Ethics, by its very nature, is pluralistic, and it is important to arrange for the creation of a forum in which various opinions will be expressed. The synthesis of these opinions will then lead to more judicious decision-making. The importance of economic growth in Québec and the development of knowledge has to go hand in hand with the protection of our values and fundamental rights, which is also the state's responsibility in a democracy. This responsibility must not be overshadowed by an infatuation with economic growth and by a marked enthusiasm for genetics.

The protection of genetic material and information, the need for legal amendments, the predominance and limits of self-regulation as a method of regulation in this field and the new values conveyed

On the legislative level, the requirements of consent and the dispositions concerning the rights to integrity, freedom, autonomy, privacy, doctor-patient privilege and confidentiality give the individual considerable means of control and protection concerning his genetic material and information. However, some legislative amendments are needed. The question of the application of the laws on access and on personal information protection to genetic material has to be clarified. Also, in light of the exceptions to confidentiality already included in these laws, the appropriateness of giving the director of professional services or the head of a hospital the power to give researchers access to a medical file without the patient's consent must be

6. Grande-Bretagne, House of Lords, Science and Technology Committee, *Human Genetic Database : Challenges and Opportunities*, March 29, 2001. In Iceland, « (o)n December 17, 1998, Althingi, the Icelandic parliament, approved legislation enabling the Ministry of Health and Social Security to grant a license to create and operate an Icelandic Health Sector Database (IHD). On January 22, 2000, Islensk erfdagreining ehf., the Icelandic subsidiary of deCODE genetics, was awarded a 12-year license to build and run the IHD. The IHD differs from similar projects elsewhere in one important respect : its nationwide scope. The database will collect information from anonymized patient records from Iceland's national health service and store the data in a secure computer system for clinical and statistical analyses. The license also permits deCODE to cross-reference IHD data with the company's genealogical database and genotypic data obtained and analyzed with the informed consent of Icelandic donors. The linkage of these three resources will create a powerful analytical tool called the deCODE Combined Data Processing system (DCDP) », site Internet de deCODE, http://www.decode.com/resources /ihd/.

revisited. It is also important to ensure that any request for access presented to the Commission d'accès à l'information be accompanied by an ethical evaluation of the research project for which the request is made.

Also, discussions on the question of the individual's moral and legal obligations towards his genetic relatives, the community to which he belongs and society have to be encouraged. There is talk of a duty of reciprocity and mutuality, of a highly ethical gesture of solidarity, that would modify fundamental social rights, such as the right to privacy. The protection of privacy, one of the fundamental aspects of individual freedom and of our democracy, is often put to the test. If the family aspect and the collective aspect of human genetics, the promising future of this sector and the particular demands of its development argue in favor of access to genetic material and information and their increased circulation, we must also debate what amounts to a choice that society as a whole must make, namely the creation and definition of a link of obligation between the individual, his family, his community and society.

Also, the federal law on the protection of personal information and electronic documents (C-6), designed to favor circulation of personal information in the commercial context and to meet the demands of e-commerce, effects in the province of Québec a radical change in philosophy concerning the respect of privacy and the protection of personal information to which we must object.

With regards to self-regulation, a rigorous framework, great caution and great vigilance must be ensured regarding the collection, conservation, use, communication and circulation of genetic material and information. To that end, rules concerning these activities must be clearly enunciated. They must be based on common principles and apply to every individual who deals with genetic material and information, to every context (not only that of research) and to every sector (private and public). Finally, they must be known and respected by all. The rules included in the documents examined, particularly regarding consent and the protection of privacy and the confidentiality of data, show a desire to participate in the management of the issues raised by genetic information. However, it must be noted that in certain instances, it is necessary to question their underlying principles and it is important to go further with these rules as regards content and implementation. These rules could be more precise; each person's obligations, duties and responsibilities must be stated unambiguously. Vague phrasing such as "the researchers should", "the researchers should insure that the participant is informed about", "the participant should be provided with options", etc. must be avoided. Accountability should be paramount.

Furthermore, the importance of the role given to research ethics committees requires that the problems they face be tackled. Particular attention must be directed

to their responsibility, to the lack of resources, to the members' training deficiencies, to the lack of uniformity in standards used, to the lack of time allocated for each research project and to the conflicts arising from the administrative links of these committees. In this respect, for the research ethics committees in the health and social services sector, the Quebec ministry of health's action plan on research ethics and scientific integrity includes certain measures whose enforcement is yet to be ensured. The Council believes it essential, however, to ensure, for research as a whole, whether in the public or private sector, the presence of local, independent, well trained and responsible ethics committees supplied with adequate professional and financial resources.

PART II : THE ROLE OF THE STATE

In the second part of this Opinion, the Council examines how to manage the issues raised, the role of the state, the values that should serve as its guidelines and formulate recommendations as regards the necessary interventions. Whether it be as administrator of public finances, provider of health services, promoter of research, protector of health and human life, arbitrator of conflicting interests, guardian of social values, legislator or protector of human rights, it is clear that the state should take on many roles in order to fulfill its democratic mandate in the context of genetics.

Values to be promoted and the responsibility of the state

Concerning the values to be promoted, the Council first reaffirms the human and social value of biomedical research which is to be measured through the improvement of individual and collective health and well-being, and which requires an ethical and legal framework whose purpose is to minimize risk and maximize benefits.

Because of the peculiarities of genetics and the speed of developments in this field, the Council also deems it important to adopt a critical attitude based on two principles : on the one hand, the principle of respect for the finality of the medical act and research activity; and, on the other hand, the principle of prudence which, most notably, renders unacceptable the urgency to proceed. It is especially because of the uncertainties which characterize research in human genetics and their practical fallout that the Council deems the principle of prudence essential. Although the sum of newly acquired knowledge in genomics is impressive, the human genome is far from having revealed all of its secrets; the precise mode of action and interaction of genes still have to be elucidated. The expected therapeutic applications stemming from research on the genetic origin of multifactorial diseases are still remote. Ten years after the discovery of the cystic fibrosis gene, a monogenic disease, there is still no effective treatment in sight.

The Council also holds that the development of genomic research and of medical genetics can and must take place with respect for the fundamental values which constitute the very basis of our democratic social contract as it has been actualized in moral culture, in the charters of rights and freedoms and in the institutions devoted to guaranteeing equal opportunity for every citizen. The intent here is not to reformulate the fundamental principles of dignity and inviolability of the individual, of autonomy and respect for privacy, of equality and solidarity, but to remind ourselves that, as soon as these principles are called into play in the name of scientific progress and economic growth, certain requirements of a philosophical order must be met, that is to say the

preservation of the internal coherence of our value systems and the representations that give them their meaning, and the evaluation of the impact of the changes on the equilibrium of these systems. It is particularly important to state these requirements in the face of pressures to modify fundamental ethical, deontological and legal rules.

The normative framework of genomic research and genetic medicine constitutes a major challenge for Québec society at a time when its economic future is following the path of cutting edge biotechnology. On the one hand, ethical and legal norms are in crisis, while unprecedented evolutive pressures descend on states from a globalized economy, imposing softer laws and diffusing the scale of economic values. On the other hand, at the very heart of Québec society, the development of genomic research and of genetic medicine has split public opinion and given rise to opposing views. The question is complex and cannot be resolved with simple and expeditious solutions : neither a rigorous legal course nor resorting to pure self-regulation can resolve every dilemma. Still, these dilemmas involve the fundamental values of the democratic social contract.

In such a situation, a large part of the responsibility must be shouldered by the state. The responsibility is to adopt a clear ideological position along two lines : first, a strong assertion that democratic values remain the foundation of a normative framework for research activities and clinical practices in human genetics; second, a commitment to maintain coherence when it comes to emerging values and ideologies, which clearly place the debate in the public arena. This requires setting up a democratic authority with the ability to conduct a political, sociological, legal and philosophical evaluation in order to launch and sustain an enlightened public debate. Such an authority will have to be structurally and financially independent from research organizations. The second responsibility of the state is to encourage recourse to open normative procedures which allow interaction between the main social players in a perspective of dialogue and self-regulation. Finally, the state also has the responsibility to include regulation incentives (strict procedures of evaluation, accreditation and sanction) and, eventually, legislative tools to ensure transparency and accountability in the self-regulation process.

Necessary interventions

To facilitate the management of the issues raised, to democratize the necessary debates, the decision-making process and the methods of regulation, the Council recommends that the state set up forums of reflection, socially and professionally, to focus on educating the public and the various care-givers, that it set up approval mechanisms favoring public participation when it comes to collecting and storing genetic material and information, and that it reinforce self-regulation. The Council believes that the

state must ensure transparency and accountability in the self-regulation process and, in this perspective, that it should arrange for the creation of effective procedures of accreditation, supervision and sanction concerning research ethics committees, which approve research protocols, and organizations from the public and private sectors which possess genetic material and information. The state must set up a basic normative framework related to the collecting, conservation and use of this material and information and make the necessary legal amendments. In a spirit of social justice and solidarity, the Council also believes that access to medical information must be restricted for employers and insurers, as must be the scope of information given to them by health professionals, that unless otherwise specified, any recourse to genetic tests in these sectors be forbidden, and that insurers be invited to rethink insurance and create a system of minimum insurance for all.

More precisely, the Council recommends the following :

- The Council recommends to the government that it set up a national authority, which could take the form of an ethics committee, and whose mandate would be to observe developments in the field of health and welfare, to conduct public consultations, to play a role in informing the public, to favor debates, to clarify social choices and to suggest, if need be, orientations aimed at making up for deficits, and to manage effectively the stakes involved. This authority could, through publications, advertising, information documents, seminars, etc., help in informing the public and the various care-givers and thus ensure a better understanding of genetics and the issues it raises. Given the various interests involved, this authority should maintain a critical independence from the government, the various ministries, research-funding agencies and the research milieu, and should also be composed mostly of representatives from the public and include representatives from several fields and sectors of activities.
- The Council recommends to the Ministry of Health and Social Services that it create communication mechanisms and forums of reflection and discussion which would allow for the necessary exchange of information, dialogue and collaboration between researchers and various health professionals.
- The Council recommends to the government that it set up, prior to the creation of any province-wide database of genetic material and information, a process of approval in which the public would play a considerable role. This process of approval could fall under the responsibility of an independent organization such as the Commission d'accès à l'information or the Protecteur du citoyen.
- The Council recommends to the Ministry of Health and Social Services that it prepare documents whose purpose is to give the public clear and accurate information on the topic of genetics.

- The Council recommends to the government that it allocate a research and education budget to the Commission d'accès à l'information so that it can promote, among the public and the various players in the sectors of health and research, rights aimed at protecting personal information, a clear understanding of the responsibilities related to this question and their application in the context of genetics.
- The Council recommends to the government that it create an organization independent from the field of research and accountable to the National Assembly, which would be given powers of accreditation, evaluation, recommendation and sanction over ethics committees and organizations from the public and private sectors in possession of genetic material and information. To ensure its accountability, this organization could fall under the responsibility of the Commission d'accès à l'information or the Protecteur du citoyen and should include researchers, doctors, ethics experts and representatives of the public, among others.
- The Council recommends to the government that it give to the proposed accreditation and supervision organization the mandate to develop a basic normative framework regarding the collection, conservation and use of genetic material and information. This normative framework could draw on the suggested standards on the topic listed in this Opinion.
- The Council recommends to the government that it modify the Act respecting access to documents held by public bodies and the protection of personal information (L.R.Q., c. A-2.1) and the Act respecting the protection of personal information in the private sector (L.R.Q., c. P-39.1) in order to ensure that they apply to genetic material.
- The Council recommends to the government that it demand an amendment to the federal law on the protection of personal information and electronic documents (C-6). This law must explicitly exclude from its application businesses subject to the Québec law on the protection of personal information in the private sector.
- The Council recommends to the government that it abrogate the exception pertaining to the confidentiality of a medical file included in article 19.2 of the Act respecting health services and social services in favor of the researchers. The researcher who wants to have access to personal information that might lead to the identification of individuals should have to ask for the consent of the people concerned. If this is not possible, he or she should have to obtain the approval of an independent organization, namely the Commission d'accès à l'information. Requests from researchers for access to information should be regulated only by articles 18, par. 8 and 21 of the Law on the private sector, and 59, par. 5, and 125 of the Law on access.

- The Council recommends to the government that it change articles 18, par. 8, and 21 of the Law on the private sector, and 59, par. 5, and 125 of the Law on access which allow communication of personal information for research purposes. These dispositions should state that any request for access in this context be accompanied by the opinion of an ethics committee certifying the merits of the research project.
- The Council recommends to the government that it develop dispositions which would specifically regulate access by employers and insurers to medical information, as well as the scope of the information supplied to them by health professionals.
- The Council recommends to the government that, through legislative means, it forbid insurers and employers to resort to genetic testing. However, if the reliability, the predictive value and the sensitivity of the projected tests have been deemed scientifically acceptable and if, in the case of employment, an exercise of reflection has taken place, exceptions to this suggested prohibition could be included :
  - for certain types of employment which entail high risk;
  - for insurance contracts exceeding a specific limit to be determined, in cooperation with insurance companies.
- The Council recommends to the government that it invite the insurance companies to create a system of minimum insurance without any inquiries pertaining to health and to adopt a code of conduct concerning the use of genetic information. In the case of failure to act within a predetermined time limit, a legislative framework to this effect should be put in place.

THE MEMBERS OF THE CONSEIL DE LA SANTÉ ET DU BIEN-ÊTRE

Mrs Hélène Morais
President

Mr André Archambault
Director General
Auberge communautaire du Sud-Ouest de Montréal

Mr Christophe Auger
Director Human Resources
Confédération des syndicats nationaux

Mrs Linda Beauchamp Provencher
Denturologist
President, administrative council, CH, CLSC and CHSLD of the MRC of Asbestos

Mr Guy Boisjoli
Consultant
Former administrator of health and social services

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CH. CHSLD. CLSC Cléophas-Claveau

Mrs Édith Deleury
Tenured Professor
Faculté de droit de l'Université Laval

Mr Jean-Pierre Duplantie
Director General
Régie régionale de la santé et des services sociaux de l'Estrie

Mrs Mireille Fillion
Associate Deputy Minister
Ministère de la Santé et des Services sociaux

Mrs Micheline Gamache
Associate Secretary
Comité ministériel du développement social

Mrs Linda Jones
Président
Fonds régional de solidarité Bas-Saint-Laurent

Mrs Marie Soleil Renaud
Psychologist
Centre de réadaptation de la Gaspésie

Mr André Thibault
Professor
Université du Québec à Trois-Rivières